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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,573	09/23/2003	Jonathan R. Coppeta	17509-0068	3038

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EXAMINER
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CORRIGAN, JAIME W

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/668,573	<b>Applicant(s)</b> COPPETA ET AL.	
	<b>Examiner</b> Jaime W. Corrigan	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.  
     4a) Of the above claim(s) 1-13, 30-34, 37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-18, 20-29, 35 and 36 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2-23-04, 6-10-04</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 30-31, 37-38, drawn to Plural distinct separators, classified in class 210, subclass 322.
- II. Claims 11-13, 32-34, drawn to For blocking passage of macromolecules , classified in class 204, subclass 403.07.
- III. Claims 14-29, 35-36, drawn to Controlled release therapeutic device or system, classified in class 604, subclass 890.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation and different effects.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with Kevin King on 5-8-06 a provisional election was made with traverse to prosecute the invention of Group III, claims 14-29, 35-36. Affirmation of this election must be made by applicant in replying to this Office action.

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Claims 1-13, 30-34, 37-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an array of microtubes, does not reasonably provide enablement for the rupturable covering. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification doesn't mention a rupturable covering for Figures 6A- 6B which would seem to best correspond to the claims elected for examination. It is unclear to the examiner whether there is one covering for all reservoirs or one covering for each reservoir.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear to the examiner which figures the elected claims are drawn to.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-17, 23, 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. (PN 5,122,128).

Regarding claim 14 Cardinal et al. discloses a single microtube (See Figure 1 (1)), the microtube comprising a reservoir (See Figure 1 (8)) defined therein; a release formulation which comprises the chemical molecules (See Figure 1 (8)), the release formulation being disposed in each reservoir (See Figure 1 (8)); a rupturable covering (See Figure 1 (5)) enclosing a first end of each reservoir; and a means (See Column 5 Lines 10-18, 27-34) for rupturing the rupturable covering and positively displacing the

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release formulation through an opening (See Figure 2a (21)) at the first end, to release the chemical molecules.

Cardinal et al. discloses the claimed invention except for an array of microtubes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to claim an array of microtubes, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 15 Cardinal et al. discloses the rupturable covering is provided with one or more defects (See Figure 2A (21)) to facilitate rupture.

Regarding claim 16 Cardinal et al. discloses the means comprises a layer of an expanding material (See Figure 1 (6)), and the release formulation (See Figure 1 (8)) is disposed between the layer of expanding material and the rupturable (See Figure 1 (5)) covering.

Regarding claim 17 Cardinal et al. discloses a layer of a barrier (See Figure 1 (7)) material is disposed between the release formulation and the expanding material;

Regarding claim 23 Cardinal et al. discloses the release formulation is a drug formulation (See Column 2 Lines 22-24).

Regarding claim 35 Cardinal et al. discloses placing the device of claim 14 at a site for release of the chemical molecules (See Abstract, Column 5 Lines 9-18); and activating the rupturing means to rupture the rupturable covering and release the chemical molecules at the site (See Abstract, Column 5 Lines 9-18).

Regarding claim 36 Cardinal et al. discloses the chemical molecules comprise a drug and the site is in vivo (See Abstract, Column 5 Lines 9-18).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. (PN 5,122,128) in view of Eckenhoff et al. (PN 4,595,583).

Cardinal et al. discloses the invention as recited in claim 14 above, however, fails to disclose the expanding material can be activated to expand upon application of heat.

Eckenhoff et al. teaches that it is conventional in the art to utilize the expanding material can be activated to expand upon application of heat (See Figure 2 (16), (17), (18), (19), Column 5 Lines 15-46).

It would have been obvious to one having ordinary skill at the time the invention was made to have utilized the heat expansive material taught by Eckenhoff et al. in the Cardinal et al. device since it would improve the timing of the release of the formulation.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. (PN 5,122,128) in view of Eckenhoff et al. (PN 4,595,583) as applied to claim 14 above, and further in view of Wong et al. (PN 6,183,466).

Cardinal et al. discloses the invention as recited in claim 14 above, however, fails to disclose a reactive coating over a portion of the microtube.

Wong et al. teaches that it is conventional in the art to utilize the means for rupturing comprises a reactive (See Column 10 Lines 59-65) coating over at least a portion of the end of the microtube distal the rupturable covering.

It would have been obvious to one having ordinary skill at the time the invention was made to have utilized the reactive coating taught by Wong et al. in the Cardinal et al. device since it would improve drug absorption.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. (PN 5,122,128) in view of Kawai et al. (PN 4,950,258).

Cardinal et al. discloses the invention as recited in claim 14 above, however, fails to disclose the the microtube is constructed of a shape memory alloy.

Kawai et al. teaches that it is conventional in the art to utilize the microtube is constructed of a shape memory alloy (See Column 2 Lines 20-25).

It would have been obvious to one having ordinary skill at the time the invention was made to have utilized the microtube shape memory alloy construction taught by Kawai et al. in the Cardinal et al. device since it would improve medical capsule medication delivery dependability.



Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. (PN 5,122,128) in view of Wong et al. (PN 6,183,466).

Cardinal et al. discloses the invention as recited in claim 14 above, however, fails to disclose the release formulation is contained in a rigid substructure within the reservoir.

Wong et al. teaches that it is conventional in the art to utilize the release formulation is contained in a rigid substructure (See Figure 2 (15), (18)) within the reservoir (See Figure 2 (14)).

It would have been obvious to one having ordinary skill at the time the invention was made to have utilized release formulation is contained in a rigid substructure within the reservoir taught by Wong et al. in the Cardinal et al. device since it would improve medication delivery safety.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. (PN 5,122,128) in view of Baumann et al. (PN 3,762,540).

Cardinal et al. discloses the invention as recited in claim 14 above, however, fails to disclose the rupturable covering comprises a metal foil.

Baumann et al. teaches that it is conventional in the art to utilize the rupturable covering comprises a metal foil (See Column 5 Lines 12-20).

It would have been obvious to one having ordinary skill at the time the invention was made to have utilized the rupturable covering comprises a metal foil taught by

Baumann et al in the Cardinal et al. device since it would improve facilitating the discharge of substances.

Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. (PN 5,122,128) in view of Neeley (PN 5,401,110).

Cardinal et al. discloses the invention as recited in claim 14 above, however, fails to disclose the microtubes are connected by and extend from a planar base; the microtubes and the planar base are constructed of a biocompatible metal; the biocompatible metal is selected from the group consisting of titanium, gold, platinum, Nitinol, and stainless steel; the microtubes are fused to the planar base by an electroplating process, an electroless plating process, or by a brazing process; the planar base is joined to a metal package, which together enclose control electronics for controlling the means for rupturing.

Neeley teaches that it is conventional in the art to utilize the microtubes are connected by and extend from a planar base (See Figures 2-3 (1), (14)); the microtubes and the planar base are constructed of a biocompatible metal (See Figures 2-3 (1), (14)); the biocompatible metal is selected from the group consisting of titanium, gold, platinum, Nitinol, and stainless steel (See Figures 2-3 (1), (14)); the microtubes are fused to the planar base by an electroplating process, an electroless plating process, or by a brazing process (See Figure 15); the planar base is joined to a metal package, which together enclose control electronics (See Figure 2 (26), (15)) for controlling the means for rupturing.

It would have been obvious to one having ordinary skill at the time the invention was made to have utilized the planar base taught by Neeley in the Cardinal et al. device since it would improve microtube storage.

### ***Allowable Subject Matter***

Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the means for rupturing comprises a resistive heating element or resistive coating for heating the end of the microtube upon application of an electric current through the resistive heating element or resistive coating, is not disclosed nor rendered obvious over the prior art of record.

### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hugemann et al. (PN 4,425,117) and Magoon et al. (4,312,347) disclose similar osmotic release systems.

Any inquiry concerning this communication from the Examiner should be directed to Examiner Jaime Corrigan whose telephone number is (571) 272-4858. The Examiner can normally be reached on Monday – Friday from 8:30 a.m. – 6:00 p.m. 2<sup>nd</sup> Friday off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kevin C. Sirmons, can be reached on (571) 272-4965. The fax number for this group is (571) 273-8300.

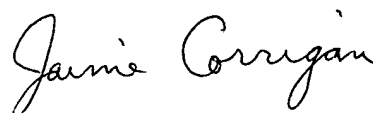
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-3700.

JC

May 11, 2006

Jaime Corrigan



Patent Examiner  
Art Unit 3767

KEVIN SIRMONS  
PRIMARY EXAMINER

